REMARKS

The Non-Final Office Action mailed June 6, 2008, has been received and reviewed. Prior to the present communication, claims 1-14, 16-23, 25-31, 33-40 and 42-51 were pending in the subject application, with claims 8, 9, 17, 25, 26, 34, 42, 43, and 51 having been withdrawn. All claims stand rejected under either § 102(e) or § 103(a). In particular, claims 1-7, 10, 12, 13, 16, 18-23, 27, 29, 30, 33, 35-40, 44, 46, 47, 49 and 50 stand rejected under 35 U.S.C. § 102(e), while claims 11, 14, 28, 31, 45 and 48 stand rejected under 35 U.S.C. § 103(a). In response, each of the independent claims 1, 18, and 35 has been amended herein, while claims 7 and 10 have been canceled and no claims have been added. Thus, claims 1-6, 11-14, 16, 18-23, 27-31, 33, 35-40, and 44-50 remain under examination. It is respectfully submitted that no new matter has been added by way of the present amendments. Reconsideration of the subject application is respectfully requested in view of the above amendments and the following remarks.

Support for Claim Amendments

Independent claims 1, 18, and 35 have been amended herein to recite clarifications of the process of providing information about the risk of an atypical clinical event based upon genetic information. In particular, the clarifications recited in claim 1 pertain to the method of automatically obtaining a genetic test result value for the associated gene of a person, where automatically obtaining now includes the steps of (a) "receiving a patient identifier of the person to whom the clinical agent is to be administered and proper authorization to access an electronic medical record (EMR) of the person," and (b) "utilizing the patient identifier and the proper authorization to access a second data set within the EMR of the person stored within a comprehensive healthcare system." Support for these claim amendments may be found in the Specification, for example, at page 13, paragraph [0037].

Additionally, the clarifications recited in claim 18 pertain to the first determining component determining whether a gene is associated with the clinical agent and "when the clinical agent is not associated with a gene from the first data set, the first determining component approves administration of the clinical agent." Support for these claim amendments may be found in the Specification, for example, at page 13, paragraph [0036]. Also, the clarifications recited in claim 18 pertain to the displaying component "displaying in a notification window a warning to the clinician that the clinical agent received from the clinician should not be administered to the person," where "the notification window surfaces a selectable area for accessing information regarding the one or more of the polymorphism values and alternative treatments thereof." Support for these claim amendments may be found in the Specification, for example, at page 18, paragraph [0048].

Further, the clarifications recited in claim 35 pertain to attempting to obtain a genetic test result value for the associated gene of the person and "when the genetic test result value cannot be obtained," (a) "calculating the likelihood that the person displays a genetic mutation linked to the gene associated with the clinical agent" based on (1) "demographic information associated with the person" or (2) "genetic variability of the gene within the general population" and (b) "constructing a message to communicate the calculated likelihood of the genetic mutation and any atypical clinical events that are associated therewith." Support for these claim amendments may be found in the Specification, for example, at pages 14-16, paragraphs [0040]-[0043], and at pages 18-19, paragraphs [0049]-[0051].

In general, amendments to the claimed subject matter are not "new matter" within meaning of 35 U.S.C. § 132 or Rule 118 of Patent Office Rules of Practice, unless they disclose an invention, process, or apparatus not theretofore described. Further, if later-submitted material

simply clarifies or completes prior disclosure, it cannot be treated as "new matter."[1] By disclosing in a patent application a device that inherently performs a function or has a property, operates according to a theory or has an advantage, "a patent application *necessarily discloses* that function, theory or advantage, even though it says nothing explicit concerning it" (emphasis added).[2] The application may later be amended to recite the function, theory or advantage without introducing prohibited new matter.[3] Accordingly, because these amendments are explicitly discussed, and/or inherent to, the procedure of providing information about the risk of an atypical clinical event based upon genetic information, as memorialized in the Detailed Description, the newly recited subject matter is encompassed by the scope of the Specification and does not constitute new matter.

Rejections based on 35 U.S.C. § 102

A.) Applicable Authority

Anticipation "requires that the same invention, including each element and limitation of the claims, was known or used by others before it was invented by the patentee."[4] "[P]rior knowledge by others requires that all of the elements and limitations of the claimed subject matter must be expressly or inherently described in a single prior art reference."[5] "The single reference must describe and enable the claimed invention, including all claim limitations,

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[1] *Trinx Co. v Hartman Metal Fabricators, Inc.*, 479 F2d 951 (1973, CA2 NY); cert. denied, 94 S. Ct. 843 (1973).

[2] *See* MPEP § 2163.07; *In re Reynolds*, 443 F.2d 384 (CCPA 1971); *In re Smythe*, 480 F. 2d 1376 (CCPA 1973).

[3] *See id.*

[4] MPEP § 2131, *passim*; *Hoover Group, Inc. v. Custom Metalcraft, Inc.*, 66 F.3d 299, 302 (Fed. Cir. 1995).

[5] *Elan Pharms., Inc. v. Mayo Foundation for Medical Educ. & Research*, 304 F.2d 1221, 1227 (Fed. Cir. 2002) (citing *In re Robertson*, 169 F.3d 743, 745 (Fed. Cir. 1999); *Constant v. Advanced Micro-Devices, Inc.*, 848 F.2d 1560, 1571 (Fed. Cir. 1988)).

with sufficient clarity and detail to establish that the subject matter already existed in the prior art and that its existence was recognized by persons of ordinary skill in the field of the invention."[6]

B.) Anticipation Rejection Based on U.S. Publication No. 2002/0110823 to Hogan

Claims 1-7, 10, 12, 13, 16, 18-23, 27, 29, 30, 33, 35-40, 44, 46, 47, 49 and 50 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Publication No. 2002/0110823 to Hogan (hereinafter the "Hogan reference"). As the Hogan reference does not describe, either expressly or inherently, each and every limitation or element of claims 1-6, 12, 13, 16, 18-23, 27, 29, 30, 33, 35-40, 44, 46, 47, 49 and 50, Applicants respectfully traverse the rejection of these claims, as hereinafter set forth. Further, claims 7 and 10 have been canceled by way of the present communication and, accordingly, the rejections of these claims have been rendered moot.

Initially, Applicants note that portions of the Hogan reference used as the basis for the anticipation rejection include elements and limitations of this subject application that are not proper prior art under § 102(e). Statute 35 U.S.C.§ 102(e) states that a person is entitled to an invention unless "the invention was described in (1) an application for patent, published under 122(b), by another filed in the United States before the invention by the application for patent . . . ." In this instance, the subject application claims the benefit of priority to U.S. Patent Application No. 09/981,248 filed October 16, 2001, which claims the benefit of priority to U.S. Provisional Application No. 60/285,263, filed April 20, 2001. April 20, 2001 predates the filing date of the Hogan reference, which was filed on October 12, 2001.

The Hogan reference is a continuation-in-part of U.S. Patent Application No. 09/613,887, filed on July 11, 2000. While the Hogan reference repeats a substantial portion of

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[6] *Id.* (emphasis added)(citing *Crown Operations Int'l, Ltd. v. Solutia Inc.*, 289 F.3d 1367, 1375 (Fed. Cir. 2002); *In re Spada*, 911 F.2d 705, 708 (Fed. Cir. 1990)). *See also, PPG Indus., Inc. v. Guardian Indus. Corp.*, 75 F.3d 1558, 1566 (Fed. Cir. 1996).

the earlier disclosure, it adds matter not disclosed in the earlier application. "A U.S. patent or patent application publication that claims the benefit of an earlier filing date under 35 U.S.C. § 120 of a prior non-provisional application would be accorded the earlier filing date as its prior art date under 35 U.S.C. § 102(e), provided the earlier-filed application properly supports the subject matter relied upon in any rejection in compliance with 35 U.S.C. § 112, first paragraph. In other words, the subject matter used in the rejection must be disclosed in the earlier-filed application in compliance with 35 U.S.C. § 112, first paragraph, in order for that subject matter to be entitled to the earlier filing date under 35 U.S.C. § 102(e)."[7] (The newly added subject matter of the CIP cannot assume the application date of the parent application.)

In this instance, subject matter in the continuation-in-part patent application (Hogan reference) that is supported by the disclosure of the parent application is entitled to the parent filing date (11-July-00), while the subject matter that is dependent on the new material added in the continuation-in-part application is entitled to a filing date that corresponds with the date the continuation-in-part is filed (12-Oct-01). The parent '887 application does not support the subject matter of the Hogan reference in paragraphs [0148]-[0150] (disclosing genomic profiling in practice) or in FIGS. 4 and 5 (depicting data sets that comprise genes, alleles, and associations with particular clinical agents) and the related discussion in paragraphs [0208]-[0216].

The Office Action, at pages 4 through 5, cites to FIGS. 4 and 5 of the Hogan reference to anticipate elements of independent claims 1, 18, and 35. These elements include (a) determining if a gene is associated with a particular clinical agent by way of comparing the identifier of the clinical agent to a first data set containing agent-gene associations, and (b) comparing the genetic test result value to a second data set containing one or more

[7] MPEP § 2163.03 (IV).

polymorphism values associated with one or more atypical clinical events for the clinical agent. Accordingly, because the parent '887 application of the Hogan reference does not disclose each and every element of claims 1, 18, or 35, the independent claims are not anticipated under § 102(e) and are in condition for allowance.

In view of the above, it is respectfully requested that the 35 U.S.C. § 102(e) rejection of independent claims 1, 18, and 35 be withdrawn. Each of claims 2-6, 12, 13, 16, 19-23, 27, 29, 30, 33, 36-40, 44, 46, 47, 49 and 50, depend, either directly or indirectly, from one of independent claims 1, 18, or 35, respectively. As such, these claims are believed to be in condition for allowance at least by virtue of their dependency.[8] Consequently, both withdrawal of the anticipation rejection and allowance of dependent claims 2-6, 12, 13, 16, 19-23, 27, 29, 30, 33, 36-40, 44, 46, 47, 49 and 50 are respectfully requested.

In addition, each of claims 1, 18, and 35 have been amended to claim distinct novel and non-obvious aspects of the present invention. It is contended that these amendments overcome the §102(e) rejection to the Hogan reference, as cited, and place the independent claims in condition for allowance. These amendments will now be discussed.

Independent claim 1, as amended hereinabove, recites a computer-implemented method for displaying a warning that a clinical agent received from a clinician should not be administered to a person. In particular, the method includes, *inter alia*, "automatically obtaining a genetic test result value for the associated gene of a person," where automatically obtaining includes (a) "receiving a patient identifier of the person to whom the clinical agent is to be administered and proper authorization to access an electronic medical record (EMR) of the person," and "(b) *utilizing the patient identifier and the proper authorization to access a second data set within the EMR* of the person stored within a comprehensive healthcare system"

[8] *See* 37 C.F.R. § 1.75(c) (2006).

(emphasis added). In this way, the proper EMR is found utilizing the patient identifier of the person and access to the EMR is provided upon submitting proper authorization, thereby securing the EMR against unauthentic requests. In addition, claim 1 recites "recording an indication of the warning in the EMR of the person" upon determining that the genetic test result value correlates to one or more of the one or more polymorphism values contained in the second data set and displaying a warning to the clinician that the clinical agent received from the clinician should not be administered.

The Hogan reference does not describe providing (a) a patient identifier of the person to whom the clinical agent is to be administered, or (b) proper authorization to access an EMR of the person. Instead, the Hogan reference describes generating a genomic profile from a sample taken from the subject, where the genomic profile is prepared in a format suitable for interpretation by a treating physician and reported thereto.[9] This profile may be stored electronically, but is not automatically accessible to extract one or more polymorphism values associated with a clinical agent. Further, the profile is not automatically located with a patient identifier or accessed with proper authorization. Instead, the Hogan reference generally discusses a "central processing facility" that stores raw data with uniform security protocols.[10] Accordingly, for at least these reasons stated immediately above, amended claim 1 and the claims that depend therefrom are not anticipated by Hogan and are in condition for allowance.

Independent claim 18, as amended hereinabove, recites a computer system for displaying a warning that a clinical agent received from a clinician should not be administered to a person. In particular, the computer system carries out a process that includes, *inter alia*, determining whether a "gene is associated with the clinical agent by comparing the identifier of the clinical agent received from the clinician to the first data set containing agent-gene

[9] *See Hogan reference* at pg. 17, ¶¶ [0187]-[0192].

associations," and "*when the clinical agent is not associated with a gene from the first data set, the first determining component approves administration of the clinical agent*" (emphasis added). In this way, a determining step is performed, and if the result of that step indicates that no gene is associated with the clinical agent, then the clinical agent is administered.

The Hogan reference does not describe proceeding with administering a clinical agent upon determining that a gene is not associated with the clinical agent. Instead, the Hogan reference describes a method for testing a sample from a subject to generate a genomic profile and subjecting the subject to a surgical procedure, where the conditions of the surgical procedure are based on the genomic profile.[11] As such, there is no specific discussion of a surgical procedure that includes proceeding with administering a clinical agent if a gene is not associated thereto.

Further, independent claim 18 is amended to recite displaying in a "notification window" a warning to the clinician that the clinical agent received from the clinician should not be administered to the person," where the "notification window surfaces a selectable area for accessing information regarding the one or more of the polymorphism values and alternative treatments thereof." In this way, additional information associated with the effects of the clinical agent may be accessed from a control (e.g., More Info button) on a user interface such that a clinician can easily gather relevant data to make an informed decision.

The Hogan reference does not describe a process that includes presenting a notification window to a clinician that includes a selectable area that provides additional pertinent information. Instead, the Hogan reference describes displaying only data to a clinician.[12] Further, Hogan does not describe presenting either (a) a warning, or (b) a selectable

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[10] *Id.* at ¶ [0192].
[11] *Id.* at ¶¶ [0015]-[0017].
[12] *Id.* at ¶ [0192].

button, but instead a risk assessment of various treatment options that a physician may use to make a recommendation. Stated another way, the computer system of the subject application is provided with the intelligence to automatically make the recommendation not to proceed with the clinical agent and to warn the clinician of this recommendation. Accordingly, for at least these reasons stated immediately above, amended claim 18 and the claims that depend therefrom are not anticipated by Hogan and are in condition for allowance.

Independent claim 35, as amended hereinabove, recites a computer-readable medium containing instructions for controlling a computer system for displaying a warning that a clinical agent received from a clinician should not be administered to a person. In particular, the process of displaying includes, *inter alia*, "attempting to obtain a genetic test result value for the associated gene of the person," and "when the genetic test result value cannot be obtained," performing the following steps: (a) "calculating the likelihood that the person displays a genetic mutation linked to the gene associated with the clinical agent based on demographic information associated with the person or genetic variability of the gene within the general population," and (b) "constructing a message to communicate the calculated likelihood of the genetic mutation and any atypical clinical events that are associated therewith." The Hogan reference, as cited, does not discuss the steps (a) or (b), or even consider a circumstance where the genetic test result value, or a "genomic profile," is not available. Accordingly, for at least these reasons stated immediately above, amended claim 35 and the claims that depend therefrom are not anticipated by Hogan and are in condition for allowance.

Rejections based on 35 U.S.C. § 103

A.) Applicable Authority

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter

as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in Graham v. John Deere counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations.[13] To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in Graham and to provide some articulated reason, suggestion, or motivation, found either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference or to combine prior art reference teachings to produce the claimed invention.[14] Recently, the Supreme Court elaborated, at pages 13-14 of the *KSR* opinion, that "it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application]."[15] Accordingly, in order to establish a *prima facie* case of obviousness, the Office shall provide a "clear articulation of the reason(s) why the claimed invention would have been obvious" based on factual findings upon applying the *Graham* factual inquiries.[16]

C.) Obviousness Rejection Based upon the Hogan reference

Claims 11, 14, 28, 31, 45 and 48 stand rejected under 35 U.S.C. § 103(a) as being obvious over the Hogan reference in view of Official Notice. As the Hogan reference and what

[13] *Graham v. John Deere Co.*, 383 U.S. 1 (1966).
[14] *See, Application of Bergel*, 292 F. 2d 955, 956-957 (1961).
[15] *KSR v. Teleflex*, No. 04-1350, 127 S.Ct. 1727 (2007).
[16] MPEP § 2143

was known to those of ordinary skill in the art at the time of invention, whether taken alone or in combination, fail to teach or suggest all of the limitations of the rejected claims. Applicants respectfully traverse this rejection, as hereinafter set forth.

It is respectfully submitted that knowledge of one of ordinary skill in the art fails to encompass the claimed features of (a) determining if a gene is associated with a particular clinical agent by way of comparing the identifier of the clinical agent to a first data set containing agent-gene associations, and (b) comparing the genetic test result value to a second data set containing one or more polymorphism values associated with one or more atypical clinical events for the clinical agent. Further, it is respectfully submitted that the knowledge of one of ordinary skill in the art at the time of invention does not encompass utilizing updatable data sets or incorporating a first data set into a second data set, as contended in the Office Action at page 8.

Rather than pointing to specific information in Hogan reference or other cited art that suggests the claimed elements above, the Office has supplemented this feature *sua sponte*. Nowhere does the Office particularly identify any suggestion or teaching, such as the identification of the relevant art, the level of ordinary skill in the art, the nature of the problem to be solved, or any other factual findings that might serve to support a proper obviousness analysis.[17] Because no specific art or documentary evidence is referenced to support this assertion, the Office has taken "Official Notice" and based the § 103(a) rejection on general skill in the art.

A prior art rejection should be based on an actual prior art reference while relying on Official Notice only where the facts asserted are well-known or of common knowledge in the

[17] *See, e.g., Pro-Mold & Tool*, 75 F.3d 1568, 1573 (Fed. Cir. 1996).

art.[18] "[Facts asserted by official notice unsupported by documentary evidence] should be of notorious character and serve only to 'fill in the gaps' in an insubstantial manner which might exist in the evidentiary showing made by the examiner to support a particular ground for rejection."[19] "It is never appropriate to rely solely on common knowledge in the art without evidentiary support in the record as the principal evidence upon which a rejection was based."[20] The present Office Action relies solely on Official Notice of alleged common knowledge in the art as the principal evidence that, when combined with the Hogan reference, forms the basis of the 35 U.S.C. § 103(a) rejection. This reliance is improper as it is used as a basis for the rejection and is not based on facts that are so well-known that they are "capable of instant and unquestionable demonstration as being well-known."[21] *A fortiori*, assertions of technical facts in areas of esoteric technology (*e.g.*, consolidating up-to-date risk assessment information based on gene-agent associations within a single data source) must always be supported by citation to some reference work recognized as standard in the pertinent art.[22] Accordingly, Applicants expressly reserve the right to request that the Examiner produce a citation to a prior art reference to support each of the 35 U.S.C. § 103(a) rejections.[23]

In this instance, the Office has not set forth the proper foundation for an Official Notice, nor established that the claimed elements above are well-known to a person of ordinary skill in the art, or may be recognized as inherent to the system of the Hogan reference. As such, the asserted general conclusion concerning what is common knowledge to one of ordinary skill in the art without some concrete evidence in the record to support this finding will not support an

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[18] MPEP § 2144.02(A); *In re Ahlert*, 424 F.2d 1088, 1091 (CCPA 1970) (finding that notice of facts beyond the record which may be taken by the Examiner must be "capable of such instant and unquestionable demonstration as to defy dispute").
[19] MPEP § 2144.03(E).
[20] *Id.*
[21] MPEP 2144.03(A).
[22] *Id.*

obviousness rejection.[24] Accordingly, the Office's assertion of Official Notice is considered traversed pursuant to MPEP § 2144.03(D).

Moreover, without demonstrating as obvious the claimed elements above, the proposed combination offered by the Office does not meet the limitations of the claimed subject matter, and as a matter of law the Office's rejection cannot stand.

[23] 37 C.F.R. § 1.104(d)(2).
[24] MPEP § 2144.03(B); *In re Lee*, 277 F.3d 1338, 1344 (Fed. Cir. 2002).

CONCLUSION

For at least the reasons stated above, each of claims 1-6, 11-14, 16, 18-23, 27-31, 33, 35-40, and 44-50 is believed to be in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned—by telephone at 816.559.2136 or via email at btabor@shb.com (such communication via email is herein expressly granted) to resolve the same prior to issuing a subsequent action.

It is believed that the fee of $1,110.00 is due in conjunction with the present communication. The Commissioner is hereby authorized to charge the amount required to Deposit Account No. 19-2112, referencing attorney docket number CRNI.114070.

Respectfully submitted.

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CERTIFICATE OF TRANSMISSION
37 C.F.R. 1.8

I hereby certify that this correspondence is being faxed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 via fax (571) 273-8300, on:

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